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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/734,241   | 12/15/2003  | Gil U. Lee           | NC 95, 996          | 2269             |
| 26384  | 7590        | 07/28/2004           | EXAMINER            |                  |
| NAVAL RESEARCH LABORATORY<br>ASSOCIATE COUNSEL (PATENTS)<br>CODE 1008.2<br>4555 OVERLOOK AVENUE, S.W.<br>WASHINGTON, DC 20375-5320 |             |                      | COUNTS, GARY W      |                  |
|  |             | ART UNIT             |                     | PAPER NUMBER     |
|  |             | 1641                 |                     |                  |
| DATE MAILED: 07/28/2004  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/734,241             | LEE ET AL.          |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Gary W. Counts         | 1641                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 17 June 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 15, 16 and 26-45 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 26-35 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16 and 36-45 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>02/18/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____ .                                  |

**DETAILED ACTION**

**Status of the claims**

The Response to Restriction Requirement filed June 17, 2004 is acknowledged and has been entered. Applicant's assessment that the Examiner reviewed the parent application without the Preliminary Amendment is found persuasive and therefore the Restriction requirement filed May 17, 2004 has been withdrawn. The current application, pursuant to the Preliminary Amendment contains Claims 15, 16, and 26-45. After consideration of the Preliminary Amendment a restriction requirement is required (See below).

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 15 and 26-35, drawn to a sensor for independently detecting a plurality of analytes in a test solution, classified in class 435, subclass 287.2.
  - II. Claims 16 and 36-45, drawn to a method for detecting a selected analyte in test solution, classified in class 436, subclass 518.
2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus can be used to practice another and materially

different process such as agricultural pesticide discovery or sample purification processes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for other restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Stephen Hunnius on July 1, 2004 a provisional election was made with traverse to prosecute the invention of Group II, claims 16 and 36-45. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15 and 26-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

5. The disclosure is objected to because of the following informalities: After the Title of the invention on page 1, the applicant fails to disclose the current status of the parent nonprovisional application(s). If a parent application has become a patent, the expression "now Patent No." should follow the filing date of the parent application. For,

example the instant application should have the expression “now Patent No. 6,676,904” should follow the filing date of the parent application.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 16 and 36-45 5 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is vague and indefinite because it is unclear how the pores retain the analyte. Are the pores of such a size that the analyte is not allowed to pass through the pores? Do the pores contain some type of substance which captures the analyte?

Claim 16 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble of the claim recites “ a method for detecting a selected analyte in test solution”, however the body of the claim does not positively recited the detection of an analyte. See also deficiency found in claim 36.

Claim 16, line 4 the recitation “the surface” there is insufficient antecedent basis for this limitation. Further, it is unclear which surface applicant is referring to. Is applicant referring to the top surface, the bottom surface or the surface within the pores?

Claim 16 is vague and indefinite because it is unclear what applicant intends to encompass by reciting “analyte contacts said membrane surface modifiers”. For example, does applicant intend a binding phenomenon occurs or do the two elements

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contact and separate. While the claim is read in light of the specification, the specification is not read into the claims. Please clarify. See also deficiency found in claim 36.

Claim 16 is vague and indefinite because it is unclear what relationship exists between the immunoassay labels, analyte and membrane modifiers. Do the labels bind to the analyte or to the membrane modifiers? Please clarify. See also deficiencies found in claim 36.

Claim 16 is vague and indefinite because it is unclear how the method works without a wash step? For example, if the immunoassay labels are not washed to remove unbound labels, there will always be a signal generated by the labels no matter if binding has occurred or not and thus there will always be a positive signal detected. Please clarify. See also deficiency found in claim 36.

Claim 36, line 2 "said pores" there is insufficient antecedent basis for this limitation.

Claim 36, line 5 "said first volume" there is insufficient antecedent basis for this limitation.

Claim 38, line 2 the recitation "is functionalized with a binder" is vague and indefinite. It is unclear if applicant is referring to the membrane modifiers or something else. For example, does the surface comprise a ligand which binds to membrane modifiers or are the membrane modifiers considered to be the functionalizing binder?

Claim 43 the recitation "an active surface" is vague and indefinite. It is unclear what surface applicant is referring to.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 16, 36, 37, 44 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Sosnowski et al (US 6,051,380).

Sosnowski et al disclose the detection of analytes (abstract). Sosnowski et al disclose contacting a sample containing the analyte (test solution) to a device. Sosnowski et al disclose that the device contains a permeation layer with selective diffusion properties (col 25, lines 13-15). Sosnowski et al disclose that this permeation layer should have a pore limit property which inhibits larger binding entities, reactants and analytes from passing through to the micro-electrode surface (col 25, lines 26-33). Sosnowski et al disclose that the permeation layer can be a porous membrane (col 25, line 45 and col 27, lines 51-53). Sosnowski et al disclose that the outer surface of the membrane is derivatized with chemical functional groups (membrane surface modifiers) (col 27, lines 52-53). Sosnowski et al discloses that these chemical functional groups binds to specific binding entities (col 28) and that these specific binding entities have affinity for another molecule (col 9). Sosnowski et al disclose that detection of binding reactions can be achieved by using labeled reporter groups and that these labels can

be conjugated to DNA or antibodies (binding ligands) (col 35, lines 35-41). Sosnowski et al disclose that the labels can be fluorescent, chemiluminescent and enzymatic (col 35, lines 35-41). Sosnowski et al disclose using an imaging or scanning detector system to detect labels (col 8). Sosnowski et al disclose that the ideal pore limit is from 2nm to 10 nm (col 27, lines 37-38). Sosnowski et al disclose that the pores allow a solvent to pass through (col 25, lines 21-24).

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 38 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al in view of Butler (US 5,137,634) and further in view of Van Damme et al (US 6,225,131).

See above for teachings of Sosnowski et al.

Sosnowski et al differ from the instant invention in failing to teach the membrane supports a 100kPa pressure load and fails to teach the membrane is an aluminum oxide membrane. Sosnowski et al also fails to teach the aluminum oxide membrane is modified by membrane modifiers.

Butler et al disclose an aluminum oxide membrane. Butler et al also disclose that this membrane supports a 110 kPa pressure load (col 7). Butler et al disclose that this membrane is resistant to chemicals and heat and that this membrane is superior to organic membranes. Butler et al also disclose that this membrane is robust to resistant accidental damage (col 1, lines 17-34).

Van Damme et al disclose aluminum oxide membranes that have immobilized binding substances on the aluminum oxide membrane. Van Damme et al also teaches that this aluminum oxide membrane provides for an improved control over the liquid distribution over the surface of a substrate and allows for assays using various optical techniques (same as Sosnowski et al).

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It would have been obvious to one or ordinary skill in the art to incorporate an aluminum oxide membrane as taught by Butler et al into the method of Sosnowski et al because Butler et al shows that this membrane is resistant to chemicals and heat and that this membrane is superior to organic membranes. Butler et al also disclose that this membrane is robust to resistant accidental damage.

Although Van Damme et al teaches that the binding substances are located within the pores, the whole membrane of Van Damme et al is comprised of aluminum oxides and one of ordinary skill in the art would be able to immobilize the binding substances on the surface of the membrane that is not within the pores. Therefore, it would have been obvious to one of ordinary skill in the art to immobilize binding substances (membrane modifiers) as taught by Van Damme et al on the surface of the modified membrane of Sosnowski et al.

14. Claims 39 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al in view of Lee et al. (US 6,180,418).

See above for teachings of Sosnowski et al.

Sosnowski et al differ from the instant invention in failing to teach the pore density of at least  $10^{15}/m^2$ . Sosnowski et al also fails to teach the membrane is coated with a biotin-polyethylene-glycol (PEG) using a polyethyleneimine layer.

Lee et al disclose coating a surface with PEG using a polyethyleneimine (PEI) layer. Lee et al disclose that this coating will be advantageous to limit nonspecific adsorption by coating the substrate with an agent that minimizes nonspecific adhesion.

It would have been obvious to one of ordinary skill in the art to coat the membrane of Sosnowski et al with PEG and PEI as taught by Lee et al because Lee et al shows that this coating will be advantageous to limit nonspecific adsorption by coating the substrate with an agent that minimizes nonspecific adhesion.

With respect to the pore density recited in the instant claims, the optimum pore density can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation.” Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation .” Id. At 458,105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

### ***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Nallur et al (US 6,692,915) disclose methods which can be performed on surfaces such as an aluminum oxide membrane (col 29, lines 58-67). Nallur et al disclose the use of fluorescent labels (col 30, lines 14-33).

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Meyerhoff et al (US 5,830,680) disclose an enzyme sandwich immunoassay in which a microporous membrane has antibodies (membrane modifiers) immobilized on its surface. Meyerhoff et al disclose labels attached to binding members (see Figure 1). Meyerhoff et al disclose that the membrane is metal coated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts  
Examiner  
Art Unit 1641  
July 7, 2004



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7/23/04